

III. Remarks

As a preliminary matter, Applicants appreciate Examiner Swiger taking the time to interview this case over the phone on September 18, 2007 with Applicant's representative to further clarify the rejection of claim 20 over the Winslow and Aebi patents as set forth in the Office Action. No exhibits were shown nor any demonstration conducted during the interview. No agreement was reached regarding claim 20.

Claims 20-29 were previously pending. No claims have been canceled. New claims 30-39 have been added. Reconsideration of pending claims 20-39 in light of the following remarks is respectfully requested.

§103 Rejections

Claim 20 stands rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,063,088 to Winslow ("the Winslow patent") in view of U.S. Patent No. 6,261,296 to Aebi et al. ("the Aebi patent").

The PTO provides in MPEP §2131 that:

"The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness."

The Examiner clearly cannot, using the Winslow and Aebi patents, establish a prima facie case of obviousness with respect to these claims for at least the following reasons.

35 U.S.C. §103(a) provides, in part, that:

"A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time of the invention was made to a person having ordinary skill in the art . . ." (emphasis added)

Thus, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated.

In the current case, even when combined the Winslow and Aebi patents do not teach the combination of elements recited in claim 20. Independent claim 20 requires, "providing an

implantation device adjacent to the alignment instrument via a clamp assembly operatively connected to the alignment instrument, the implantation device holding the prosthetic device at a distal end thereof.” In this regard, the Examiner recognizes that the Winslow patent fails to disclose a clamp assembly as explicitly required by claim 20. The Office Action asserts that, “Aebi et al. disclose a clamp assembly to hold an implantation device adjacent to the alignment instrument (see Fig. 1, 44a and b) to provide a step for insertion of a prosthesis.” However, the distractor blades 44a, 44b of the Aebi patent are utilized for engaging and distracting vertebrae. The distractor blades 44a, 44b are not connected to an alignment instrument as required. Further, even if the distractor blades 44a, 44b of the distractor 10 are considered the clamp assembly, it is unclear what component of the Winslow or Aebi patents could be considered the implantation device, as the implantation device must be adjacent to the alignment instrument and hold a prosthetic device at a distal end. If the distractor blades 44a, 44b are connected to a alignment instrument, as required, then it is unclear how the distractor 10 could also be utilized to hold a prosthetic device. Accordingly, for at least these reasons even when combined the Winslow and Aebi patents fail to disclose all of the recited elements of claim 20.

Second, there is no reason for combining the distractor blades of Aebi with the method of Winslow. Recently, the Supreme Court ruled that the “teaching, suggestion, or motivation (TSM) test” still applies, but should be used in a more “expansive and flexible” manner. *KSR Int’l. Co. v. Teleflex Inc.*, 550 U.S. ___, 11 (2007). The Court stated that

“A patent composed of several elements **is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.** Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a **reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.** This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” *Id.* at 14-15, emphasis added.

In the present case, the Examiner has not expressed any reason why a person of ordinary skill in art would combine the distractor blades 44a, 44b of the Aebi patent with the method of the Winslow patent. First of all, the Office Action did not provide a single reason for combining the Aebi and Winslow patents. Rather, the paragraph setting forth the rejection ends mid-sentence before setting forth any reasons for combining the patents. Further, after discussing this rejection with the Examiner, Applicants are still unclear how these references could be combined to teach the claimed limitations and—assuming the references can be combined somehow—what the reason for combining the references would be. It is simply unclear how or why the distractor blades 44a, 44b of the Aebi patent would be combined with the retractor 100 of the Winslow patent. As far as Applicants can tell, there is no reason to combine these aspects of the Winslow and Aebi patents other than using hindsight in an attempt to reconstruct the present invention, which is prohibited.

Therefore, for at least these reasons the Examiner's burden of establishing a prima facie case of obviousness has clearly not been met with respect to independent claim 20. Applicants respectfully request that the §103 rejection of claim 20 over the Winslow and Aebi patents be withdrawn.

Claim 21 stands rejected under 35 U.S.C. §103(a) as being unpatentable over the Winslow patent in view of the Aebi patent as applied to claim 20, in further view of U.S. Patent No. 6,283,966 to Houfburg ("the Houfburg patents"). Claim 21 depends from and further limits claim 20. As noted above, however, the Winslow and Aebi patents are insufficient to support a prima facie case of obviousness with respect to claim 20. The Houfburg patent does not affect this deficiency. Thus, for at least the same reasons, even when combined the Winslow, Aebi, and Houfburg patents cannot support a §103(a) rejection of claim 21. Therefore, the Examiner's burden of factually supporting a prima facie case of obviousness has clearly not been met.

Further, claim 21 recites, "wherein aligning the alignment instrument comprises aligning a radiographic marker disposed within the alignment instrument via a fluoroscopic machine." However, as set forth in Applicant's previous response, Houfburg does not teach having a radiographic marker disposed within an alignment device. Rather, in the portion Houfburg cited

by the Office Action, radiographic templating is discussed in the context of determining an appropriate implant size. There is simply no disclosure of a radiographic marker being disposed within an alignment instrument. Thus, Houfburg clearly does not teach aligning the alignment instrument by aligning a radiographic marker disposed within the alignment instrument as required. Therefore, for this additional reason even when combined the Winslow, Aebi, and Houfburg patents fail to teach all of the recited elements of claim 21. Thus, for at least this additional reason the Examiner's burden of factually supporting a prima facie case of obviousness has clearly not been met, and Applicants respectfully request that the §103(a) rejection of claim 21 be withdrawn.

Claim 22 stands rejected under 35 U.S.C. §103(a) as being unpatentable over the Winslow patent in view of the Aebi patent as applied to claim 20, in further view of U.S. Patent No. 6,302,890 to Leone, Jr. ("the Leone patent"). Claim 22 depends from and further limits claim 20. As noted above, however, the Winslow and Aebi patents are insufficient to support a prima facie case of obviousness with respect to claim 20. The Leone patent does not affect this deficiency. Thus, for at least the same reasons, even when combined the Winslow, Aebi, and Leone patents cannot support a §103(a) rejection of claim 22. Therefore, the Examiner's burden of factually supporting a prima facie case of obviousness has clearly not been met, and Applicants respectfully request that the §103(a) rejection of claim 22 be withdrawn.

Claims 23-29 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Winslow patent in view of the Aebi patent as applied to claim 20, in further view of U.S. Patent No. 5,643,286 to Warner et al. ("the Warner patent"). Claims 23-29 depends from and further limit claim 20 either directly or indirectly. As noted above, however, the Winslow and Aebi patents are insufficient to support a prima facie case of obviousness with respect to claim 20. The Warner patent does not affect this deficiency. Thus, for at least the same reasons, even when combined the Winslow, Aebi, and Warner patents cannot support a §103(a) rejection of claims 23-29. Therefore, the Examiner's burden of factually supporting a prima facie case of

obviousness has clearly not been met, and Applicants respectfully request that the §103(a) rejection of claims 23-29 be withdrawn.

New Claims

New claims 30-39 have been added and include limitations not disclosed or suggested by the Winslow, Aebi, Houfburg, Leone, and Warner patents. For example, new independent claim 30 requires:

“providing an alignment instrument having an anchoring device for engaging a vertebra extending from a distal end thereof;
providing an insertion instrument for inserting a implant;
providing a first clamp assembly for engaging with the alignment instrument;
providing a second clamp assembly for engaging with the first clamp assembly and engaging with the insertion instrument;
positioning the insertion instrument adjacent to the alignment instrument; and
connecting the insertion instrument to the alignment instrument via the first and second clamp assemblies.”

New independent claim 35 requires:

“providing an alignment instrument having a bone anchoring device extending from a distal end thereof;
providing an insertion instrument having an implant engaging portion;
providing a clamp assembly for connecting the insertion instrument to the alignment instrument;
engaging the anchoring device of the alignment instrument with a vertebra adjacent to an intervertebral space;
aligning the alignment instrument relative to the intervertebral space;
securing the alignment instrument in the aligned position;
engaging an implant to the implant engaging portion of the insertion instrument;
connecting the insertion instrument to the alignment instrument via the clamp assembly; and
inserting the implant into the intervertebral space with the insertion instrument.”

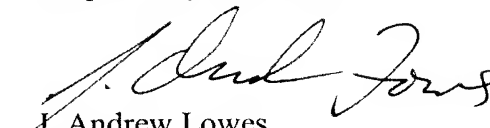
Accordingly, Applicants believe that new claims 30-39 are patentable over the cited references.

IV. Conclusion

It is believed that all matters set forth in the Office Action have been addressed, and that claims 20-39 are in condition for allowance. An early notice of allowability is respectfully requested.

Should the Examiner deem that an interview with Applicants' undersigned attorney would expedite prosecution, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,


J. Andrew Lowes
Registration No. 40,706

Dated: September 21, 2007
HAYNES AND BOONE, LLP
901 Main Street, Suite 3100
Dallas, Texas 75202-3789
Telephone: 972-680-7557
IP Facsimile No. 214-200-0853
R-176332_1.DOC

Certificate of Service
I hereby certify that this correspondence is being filed with the U.S. Patent and Trademark Office via EFS-Web on September 21, 2007.
 Gayle Conner